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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/873,601 06/12/97 NOLAN

G A-63915/DJB/

HM22/0116
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EXAMINER

WESSENDURF, T

ART UNIT	PAPER NUMBER
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1627 *24*

DATE MAILED:

01/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/873,601	Applicant(s) Nolan et al
	Examiner T. Wessendorf	Group Art Unit 1627

Responsive to communication(s) filed on 11/2/00

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 44-50 and 52-57 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) 44-50 and 52-57 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1627

Newly submitted claim 51 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim is drawn to a library of precursor, different from the originally submitted precursor i.e., not a library.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 15 is withdrawn from consideration as being directed to a non-elected invention. See 37 CAR 1.142(b) and MPEP § 821.03.

Claims 44-50 and 52-57 are pending in the application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-50 and 52-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action, 8/6/99, page 4, paragraph 11 up to page 5.

Art Unit: 1627

✓ It is argued that the specification defines fusion partner as a sequence that is associated either with the nucleic acid or the expression product that confers a common function. However, claim 44 does not recite an expression product. Claim 45 recites a nucleic acid but unclear as to how the fusion partner is associated with the nucleic acid, especially in the absence of positive showing in the specification of a fusion partner of said nucleic acid. It is further argued that the specification discloses several examples of fusion partners e.g., targeting sequences, rescue sequences etc. As the rejection stated, the metes and bounds of fusion partners are not clearly set forth in the claims. The argued sequences are limitations not in the claims. The specification defines said fusion in functional term rather than the structure by which it is associated to the nucleic acid that would confer a common(?) function, especially in the absence of any showing that the fusion partner confers a common function or ability to the nucleic acid.

Applicants argue that when a composition is introduced into cells , the scaffolds are preferably, an exogenous scaffold. Exogenous scaffold is argued to meant as not naturally occurring within the cell or does naturally occur within the cell but is present at either a significantly higher concentration than is

Art Unit: 1627

normally seen within the cell or in a form not normally seen in the cell. However, it is not seen how this is applicable to a composition wherein the scaffold is the only exogenous component and not the other components of the composition. Are applicants implying that the scaffold when introduced to a cell, is bound thereto by different enzymes, at the specifically indicated positions or claimed sites of the scaffold, i.e., first enzyme to the first location of the scaffold etc.? Furthermore, it appears that whether a substance is exogenous or not depends on whether it is introduced into a component and not whether it is present in a small or abnormally high concentration, as argued.

Claim 44 is indefinite as to the differentiating characteristics between binding and biological reaction, within the claimed context, especially since the metes and bounds of the recited scaffold and enzymes are not clearly set forth in the claims.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 44-50 and 52-57 are rejected under 35 U.S.C. 101 because of the reasons set forth at paragraph 13, pages 6-7 of the last Office action.

Art Unit: 1627

Since applicants have not provided arguments why the instant cell would not read on known natural products, hence the rejection under this statute is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-50, 52-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of the claimed invention wherein the enzymes do not biologically react with the scaffold as there is not a single showing in the specification of non-biological reaction (is this different from binding?). The specification merely recites said function but does not show how enzymes present in a cell did not biologically react with the scaffold, especially when the exogenous scaffold, as broadly claimed, can be any material to which an enzyme can (non-covalently) react (or bind).

Art Unit: 1627

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 44-50 and 52-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Khosla et al for reasons of record, pages 7-9 of the last Office action.

Applicants argue that the structure of the DEBS multi-enzyme complex comprising the three proteins has not been determined yet and is not known if one of the three proteins provides binding sites for the other two proteins. This is irrelevant especially since the claims do not recite for any structure and would read on the claims which merely recites the capability of the enzymes to bind to the scaffold. It is argued that the protein (third, scaffold) of Khosla reacts with the enzymes which is precluded by

Art Unit: 1627

the claims. While the claims recite said functional exclusion however, in the absence of any showing in the specification and the recitation of any scaffold not precluding a biological scaffold hence, the claimed exclusion is not clear, especially in a cell where complex or all sorts of binding or reaction of the components present therein can occur.

Claims 44-50 and 52-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Horowitz as evidenced by the teachings of Zhao and Padmanabah for reasons set forth in the last Office action.

Applicants recognize that adenoviruses act as scaffold to which the enzymes RNA and DNA binds to but argue that the enzymes biologically react with the adenovirus scaffold. But the claims recite broadly any scaffold and enzyme present in a cell for which biological binding or reaction to a scaffold can be biological. In the absence of any showing in the specification and for a claim broadly claiming any kind of scaffolds and enzymes, hence, the specific composition of Horowitz contain in the cell would meet the broad claimed invention.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

Art Unit: 1627

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

Art Unit: 1627

DUPPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
T. Wessendorf
Patent Examiner
Art Unit 1627
1/12/01